

SUBCHAPTER B—MEDICARE PROGRAM

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

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AUTHORITY: 42 U.S.C. 263a, 405(a), 1302, 1320b-12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

Subpart A [Reserved]

Subpart B—Medical Services Coverage Decisions That Relate to Health Care Technology

AUTHORITY: Secs. 1102, 1862 and 1871 of the Social Security Act as amended (42 U.S.C.1302, 1395y, and 1395hh).

SOURCE: 60 FR 48423, Sept. 19, 1995, unless otherwise noted.

§ 405.201 Scope of subpart and definitions.

(a) *Scope.* This subpart establishes that—

(1) CMS uses the FDA categorization of a device as a factor in making Medicare coverage decisions; and

(2) CMS may consider for Medicare coverage certain devices with an FDA-approved investigational device exemption (IDE) that have been categorized

as Category B (Nonexperimental/investigational) device.

(3) CMS identifies criteria for coverage of items and services furnished in IDE studies.

(b) *Definitions.* As used in this subpart—

Category A (Experimental) device refers to a device for which “absolute risk” of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective.

Category B (Nonexperimental/investigational) device refers to a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type.

ClinicalTrials.gov refers to the National Institutes of Health’s National Library of Medicine’s online registry and results database of publicly and privately supported clinical studies of human participants conducted around the world.

Contractors refers to Medicare Administrative Contractors and other entities that contract with CMS to review and adjudicate claims for Medicare payment of items and services.

Investigational device exemption (IDE) refers to an FDA-approved IDE application that permits a device, which would otherwise be subject to marketing approval or clearance, to be shipped lawfully for the purpose of conducting a clinical study in accordance with 21 U.S.C. 360j(g) and 21 CFR part 812.

Routine care items and services refers to items and services that are otherwise generally available to Medicare beneficiaries (that is, a benefit category exists, it is not statutorily excluded, and there is no national non-coverage decision) that are furnished during a clinical study and that would